

SEP 15 2000

DS i-series™
SMV

Section M. 510 (k) Summary Of Safety And Effectiveness

Special 510 (k): Device modification

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K002553
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Section M. 510 (k) Summary Of Safety And Effectiveness

(The following information is in conformance with 21 CFR 807.92.)

Date Prepared

June 30, 2000

Establishment Name and Registration number of submitter

Name: SMV America
8380 Darrow Road
Twinsburg, Ohio 44087

Registration number: 1528274

Contact: Lonnie Mixon

Device name and classification

Classification Code: 90 KPS

Panel Identification: Radiology

Proprietary Name: DS i-series

Common Name: Gamma Camera System

Classification Name: System, Emission Computed Tomography

Classification Class: Class II Product

Reason for 510(k) submission Device Modification

Device Description

The DS i-series resulted from a modification of the DST-XL (Modified DST Nuclear imaging system), listed by the FDA under 510k N°K942837, and incorporates a modified gantry designed to integrate the acquisition electronics. The modifications do not change the fundamental scientific technology nor the intended use of the original device, and do not affect the safety and effectiveness of the device.

The DS i-series supports single or dual head configurations, which can be either wide or large rectangular field of view. The design allows all single head configurations to be upgradeable to dual head.

The DS i-series allows four camera configurations all on the same gantry using the same robotics, the same electronics, and the same software; only the detectors and head configuration are different.

The name of the four cameras of the DS i-series are DST-XLi dual-head, variable-angle camera extra large detector; the DSXi single-head, variable-angle camera extra large detector; the DSTi dual-head variable-angle camera wide field detector; and the DSi rectangular single-head, variable-angle wide field detector.

The DS i-series supports all previously listed SMV options as VCAR (510k N°K972686), TAC (510k N°K952190) and TAC-2 (510k N°K991565).

Intended Use

The modification will not change the intended use. As in the original device, the DS i-series is intended for use as a diagnostic imaging device. Used with appropriate radiopharmaceuticals it produces images, which depict the functional distribution of radioisotopes within the human body for interpretation by medical personnel.

Technological Comparison

The DS i-series is similar to the DST-XL (Modified DST Nuclear imaging system), listed by the FDA under 510k N°K942837. It is similar in the intended use, similar on the technical specifications, and similar on the performances.

The changes when compared with the original design are the name and the mechanics. The mechanical change permits the integration of the complete electronics in the gantry instead of being located on a external cabinet.

Testing

Major performance parameters have been measured using industry-standard test methods to determine that the device meets its specifications and performs in a fashion similar to original devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 2000

Lonnie Mixon
Vice President of Marketing
SMV America
8380 Darrow Road
Twinsburg, OH 44087

Re: K002553
DS I-Series
Dated: August 31, 2000
Received: September 7, 2000
Regulatory Class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Mixon:

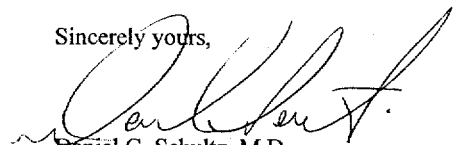
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Section D. Indications for Use Form

510(k) Number (if known): K002553

Device Name: DS i-series

Indications For Use:

The DS i-series Gamma Cameras systems are intended for use as diagnostic imaging devices. Used with appropriate radiopharmaceuticals, they produce images, which depict the functional distribution of radioisotopes within the human body for interpretation by medical personnel.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device (ODE)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002553

Prescription Use ✓
(Per 21 CFR 801.109)

(Optional Format 3-10-98)